added. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed January 23, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claims 2-13 without prejudice. In addition, claim 1 has been amended to delete unelected subject matter of part (b). However, in accordance with the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

Applicants have also added dependent claim 15 to the species elected in response to the Restriction Requirement. No new matter is added by this amendment.

II. Objection to Specification

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner suggests that the disclosure makes no mention of using a vaccine in the treatment of colon cancer as

set forth in claim 14.

Applicants respectfully disagree.

Use of CSGs of the present invention as vaccines in the treatment of colon cancer is disclosed in detail in the specification at page 38, line 1 through page 40, line 13. Thus, contrary to the Examiner's suggestion, the specification provides adequate antecedent basis for claim 14.

It is respectfully pointed out, however, that claim 14 has been canceled, thus mooting this objection.

Withdrawal of this objection is respectfully requested.

III. Rejection of Claims 1 and 14 under 35 U.S.C. § 112, first paragraph

Claims 1 and 14 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner has acknowledged the specification to enabling for an isolated polynucleotide comprising SEQ ID NO:5. However, the Examiner suggests that the specification does not reasonably provide enablement for a variant of a polynucleotide comprising SEQ ID NO:5 or a polynucleotide capable of hybridizing to the antisense sequence of SEQ ID NO:5. Further, the Examiner suggests that the specification provides no exemplification of or guidance on how

to use the claimed vaccine in the treatment of colon cancer.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to remove the phrase "or variant thereof." Further Applicants have amended part (c) to clarify that the polynucleotide has 95% identity to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22. Support for this amendment is provided in the specification at page 18, lines 10-17. Clearly undue experimentation would not be required to practice the invention as now claimed in claim 1.

With respect to claim 14, Applicants respectfully disagree with the Examiner's suggestion that the specification provides no guidance on how to use the claimed vaccine in the treatment of colon cancer. As discussed in Section II, *supra*, use of CSGs of the present invention as vaccines in the treatment of colon cancer is disclosed in detail in the specification at page 38, line 1 through page 40, line 13. Further, Applicants disagree with the Examiner that references from 1995 and 1997 are representative of "current thinking in cancer vaccines".

However, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 14.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, with respect to lack of enablement is respectfully requested.

Claims 1 and 14 have also been rejected under 35 U.S.C. § 112, first paragraph as the Examiner suggests that the specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. Specifically, the Examiner suggests that the specification does not disclose the isolation of and assaying of molecules, or any variants of SEQ ID NO:5. The Examiner also suggests that there is no actual reduction to practice, sufficient descriptive information, such as definitive structural features, which are critical to polypeptide activity, or complete detailed description of the function of the claimed invention indicating that the claimed nucleic acids were indeed isolated, produced and assayed for the use disclosed. In addition, the Examiner suggests that there are no examples disclosed that convey to one of skill in the art that the applicant was in possession of any vaccine for the treatment of colon cancer, as there is no descriptive information, such as how to make and

administer the vaccine or complete detailed description of the function of the claimed invention indicating that the vaccine was indeed identified and used for the treatment of colon cancer.

Applicants respectfully traverse these rejection.

At the outset, it is respectfully pointed out that claim 1 has been amended to remove reference to variant sequences and polypeptides. Accordingly, the Examiner comments relating to any variants of SEQ ID NO:5 and actual reduction to practice, sufficient descriptive information, such as definitive structural features, which are critical to polypeptide activity are no longer relevant. Also irrelevant are the Examiner's comment relating to the vaccine of claim 14 as this claim has been canceled by this amendment.

Applicants respectfully disagree with the Examiner's suggestion that there is no detailed description of the function of the claimed invention indicating that the claimed nucleic acids were indeed isolated, produced and assayed for the use disclosed. The Examiner is respectfully directed to page 81, line 29 through page 82, line 39, wherein details of CLASP experiments identifying each of the CSGs of the present invention are described in detail. Further, the Examiner is respectfully directed to pages 83-86 wherein the exemplary CSG of SEQ ID NO: 5

is demonstrated to be a diagnostic marker for colon cancer. Clearly, these teachings show Applicants' possession of the CSGs of claim 1.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for written description is respectfully requested.

IV. Rejection of Claim 1(c) under 35 U.S.C. § 102(b)

Claim 1(c) has been rejected under 35 U.S.C. § 102(b) as being anticipated by Peinado et al. (1992). The Examiner suggests that Peinado et al. teach arbitrarily primed polymerase chain reaction (AP-PCR) to detect somatic genetic alterations in tumors of the colon and rectum using arbitrary primers, which hybridize under stringent conditions to numerous sequences in the total genomic DNA. The Examiner suggests that it is inherent that the polynucleotide primer may hybridize to a portion of antisense sequence of SEQ ID NO:5 under stringent conditions.

Applicants respectfully traverse this rejection.

As discussed in Section III, *supra*, part (c) of claim 1 has been amended to clarify that the polynucleotide has 95% identity to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22. Support for this amendment is

found at page 18, lines 10-17 of the instant specification. No where does Peinado et al. teach polynucleotides with 95% identity to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22. Thus, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection is therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

Respectfully submitted,

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Date: **August 21, 2002**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 2-14, without prejudice.

Please amend the claims as follows:

1. (amended) ~~An~~ CSG comprising:

(a) a polynucleotide of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22~~, or a variant thereof,~~

~~(b) a protein expressed by a polynucleotide of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22, or a variant thereof,~~ or

~~(c)~~ (b) a polynucleotide with 95% identity to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, or 22 which is capable of hybridizing under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22.